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Milk Thistle

Revised: March 15, 2023.

CASRN: 84604-20-6

Drug Levels and Effects

Summary of Use during Lactation

Milk thistle (*Silybum marianum*) contains silymarin, which is a mixture of flavonolignans, mainly silibinin (also known as silybin), as well as silycristine, silydianin, quercetin and taxifolin.[1] Silymarin is a standardized preparation extracted from the fruits (seeds) of milk thistle. Milk thistle is a purported galactogogue,[2] and is included in some proprietary mixtures promoted to increase milk supply; however, no scientifically valid clinical trials support this use.[3-5] Although a study on the high potency purified milk thistle component, silymarin, and a phosphatidyl conjugate of silymarin indicated some galactogogue activity, this does not necessarily imply activity of milk thistle itself. Galactogogues should never replace evaluation and counseling on modifiable factors that affect milk production.[6,7]

Limited data indicate that the silymarin components are not excreted into breastmilk in measurable quantities. Additionally, because silymarin components are poorly absorbed orally, milk thistle is unlikely to adversely affect the breastfed infant. Milk thistle and silymarin are generally well tolerated in adults with only mild side effects such as diarrhea, headache, and skin reactions. Mothers taking milk thistle to increase milk supply reported weight gain, nausea, dry mouth and irritability occasionally. Milk thistle might increase the metabolism of some drugs. Rarely, severe allergies and anaphylaxis are reported. Avoid in patients with known allergy to members of the aster (Compositea or Asteraceae) family, such as daisies, artichokes, common thistle, and kiwi because cross-allergenicity is possible.

Dietary supplements do not require extensive pre-marketing approval from the U.S. Food and Drug Administration. Manufacturers are responsible to ensure the safety, but do not need to *prove* the safety and effectiveness of dietary supplements before they are marketed. Dietary supplements may contain multiple ingredients, and differences are often found between labeled and actual ingredients or their amounts. A manufacturer may contract with an independent organization to verify the quality of a product or its ingredients, but that does *not* certify the safety or effectiveness of a product. Because of the above issues, clinical testing results on one product may not be applicable to other products. More detailed information about dietary supplements is available elsewhere on the LactMed Web site.

Drug Levels

Silibinin has low and variable bioavailability of 23 to 47% after oral administration and is rapidly converted into glucuronide conjugates that have longer half-lives in plasma than the unconjugated forms.[8]

Maternal Levels. Five mothers who had decided to stop nursing because their infants were 9 months old were given 600 mg of micronized silymarin (BIO-C brand) orally 3 times daily. After 5 days of therapy, milk was collected at unspecified times for analysis by HPLC. Silymarin flavonolignans were undetectable (<1 mcg/L) in milk samples; however, their conjugated forms might not have been detected by the assay method used.[9]

Silymarin metabolites (silychristin, silydianin, silibyn A, silibyn B, isosilybin A and isosilybin B) were not detected (<0.3 mg/kg) in breastmilk of any of 25 women studied on day 14 of treatment with micronized silymarin 252 mg (BIO-C) twice daily.[10]

Infant Levels. Relevant published information was not found as of the revision date.

Effects in Breastfed Infants

A study compared a commercial product containing silymarin 252 mg (BIO-C) to placebo every 12 hours in mothers of preterm (<32 weeks) infants. No adverse effects were observed in any of the infants.[10]

In a study of galactogogue containing 5 grams of a mixture of silymarin, phosphatidylserine and galega (goat's rue) in an unspecified proportion and from an unspecified source, none of the typical adverse effects of silymarin were noted in the breastfed infants.[11]

Effects on Lactation and Breastmilk

No human data are available on the effect of milk thistle or its components on serum prolactin. A study in gilts (female domestic pigs) found that silymarin 4 grams twice daily during pregnancy and lactation found that serum prolactin levels were increased compared to gilts given placebo. The slight increase in prolactin had no effect on mammary gland development, nor on plasma progesterone or estradiol.[12]

A study was performed on 50 medically normal postpartum mothers with milk production judged to be less than normal for patients in the hospital in Lima, Peru where the study was conducted. Mothers were divided non-randomly into 2 groups of 25 women who had identical ages, weights, number of children and newborn's age, although ages were not reported. The group that was given micronized silymarin (BIO-C brand) 420 mg daily for 63 days had a baseline milk production of 602 mL daily. The milk volumes and composition (water, fats, carbohydrate and protein) of the 2 groups were not significantly different on day 0. The group given an identical placebo had a baseline milk production of 530 mL daily. Milk production was measured on day 30 and day 63 by infant weighing before and after nursing followed by emptying the breasts with a breast pump. The composition of the milk was also determined. Statistically significant differences in average milk production were found on day 30 (990 grams in the silymarin group and 650 grams in the placebo group) and on day 63 (1119 grams in the silymarin group and 701 grams in the placebo group). Milk composition was not different between the groups at the two time points.[9] Deficiencies in this study include the lack of randomization, no investigator blinding, and no optimization of breastfeeding technique prior to study enrollment. Also, breastfeeding duration and long-term infant growth were not studied.

In a randomized, double blinded study, a placebo (5 grams of lactose) or a commercial product (Piùlatte Plus, Milte) containing 5 grams of a mixture of silymarin, phosphatidylserine and galega (goat's rue) was given once daily to mothers of preterm infants. Phosphatidylserine purportedly improves the bioavailability of silymarin. The medication or placebo was given from day 3 to day 28 postpartum. Mothers pumped using a breast pump every 2 to 3 hours during the day and as desired at night. Milk production was measured on days 7, 14 and 28 postpartum. Daily milk production averaged 200 mL in the treated group and 115 mL in the control group. The

total amount of milk produced during the study period and the proportion of women producing more than 200 mL daily was greater in the treated group than controls on days 7 and 28.[11] Mothers were contacted at 3 and 6 months postpartum concerning breastmilk production. Of the 89 mothers who responded satisfactorily at 3 months, more mothers who had received silymarin-galega were exclusively breastfeeding than those who received placebo (22/50 vs 12/50). Also, more mothers were feeding more than 50% breastmilk to their infants in the treatment group than the placebo group (29/50 vs 18/50). At 6 months postpartum, more mothers were feeding more than 50% breastmilk to their infants in the treatment group than in the placebo group (22/50 vs 12/50). These differences were statistically significant.[13]

A randomized study compared a commercial product containing micronized silymarin 252 mg (BIO-C) to placebo every 12 hours in mothers of preterm (<32 weeks) infants, beginning at 10 days postpartum. Mothers used a breast pump 6 times daily and measured milk output before beginning, 5 times during the 28 days of treatment, and on days 36 and 45. No difference in milk production was observed between the two groups at any time point. The mothers' guesses of whether they had taken placebo or silymarin were no better than chance.[10]

In a survey of 188 nursing women from 27 states (52% from Louisiana), 24 had used milk thistle as a galactogogue. Of those who used it, 52% were not sure that it increased their milk supply and 4 reported unspecified side effects.[14]

In a survey of nursing mothers in Australia, 40 mothers were taking milk thistle as a galactogogue. On average, mothers rated milk thistle as being between “slightly effective” and “moderately effective” on a Likert scale. Ten percent of mothers taking milk thistle reported experiencing adverse reactions, most commonly weight gain, nausea, dry mouth and irritability.[15]

A retrospective study was performed in a Greek hospital on 161 mothers who were given Silitidil (a standardized extract consisted of 33% silymarin, 33% lecithin and 33% phosphatidylserine supplied as Piùlatte by Humana) 5 grams daily for 14 days. Mothers who were given Siltidil had twins or premature newborns, or whose neonates had weight loss greater than 10% of body weight, needed phototherapy, or required transport to a tertiary intensive care unit, and mothers unable to breastfeed due to any other reason. Telephone follow-up was done at 10 days, 1, 4 and 6 months. Breastfeeding rates (exclusive and nonexclusive) were 100% during their first week, 98.8% during the first month, 87% during the first 4 months, 56.5% at 6 months, 41% at 1 year and 19.3% over 1 year of age.[16] The retrospective nature of this study and lack of a control group, blinding, and characterization of breastfeeding, among other problems, make this paper impossible to interpret.

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Substance Identification

Substance Name

Milk Thistle

Scientific Name

Silybum marianum

CAS Registry Number

84604-20-6

Drug Class

Breast Feeding

Lactation

Milk, Human

Antioxidants

Complementary Therapies

Galactogogues

Phytotherapy

Plants, Medicinal

Protective Agents